

REMARKS

Claims 1-40 are pending in the application, of which claims 1-7, 11-13, and 32-34 are under examination. Claims 1, 11, and 32 were amended to more clearly claim what Applicants consider to be their invention. Claims 3, 10, 13, 15-31, and 34-40 are canceled in order to expedite prosecution of the present application. In a telephone interview, the Examiner has agreed to rejoin previously withdrawn claims 8, 9, and 14 (discussed below).

Claims 11-13 are rejected as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention under 35 U.S.C. § 112, second paragraph. Claims 1-7, 11, 12, 32, and 33 are rejected as allegedly lacking sufficient enablement under 35 U.S.C. § 112, first paragraph. Claim 11 is objected to as being dependent upon a non-elected claim. Claim 34 is objected to as being dependent upon a rejected base claim. Applicants respectfully submit that the amended claims should be construed as being submitted merely to clarify the invention rather than as submitted to overcome a cited reference. Additionally, for the purposes of any forthcoming legal proceedings involving a patent that may issue, Applicants reserve the right to dispute the Office Action's assertion of effective priority.

I. Examiner Interview

Applicants thank the Examiner for the phone interview on July 25, 2007 discussing the allowability of the amended claims. The amended claims now address the objections and the 35 U.S.C. § 112 rejections. Also, as discussed, the Examiner agreed to rejoin previously withdrawn claims 8, 9, and 14. Applicants thank the Examiner for the rejoinder of the claims.

II. Claim Objections

A. Claim 11

Claim 11 is objected to as being dependent upon a non-elected claim, specifically claim 9. Accordingly, Applicants have amended claim 11 to remove the dependency. Support for this amendment can be found in the detailed description at least in paragraphs 42, 44, and 97-103. Accordingly, applicants believe the objection is overcome by the claim amendments and request withdrawal of the objection.

B. Claim 34

Claim 34 is objected to as being dependent upon a rejected base claim. Accordingly, Applicants have canceled claim 34 and incorporated the limitations of claim 34 into independent claims 11 and 32. Support for this amendment can be found in the detailed description at least in paragraphs 32, 51, and 52. Accordingly, applicants believe the objection is overcome by the claim amendments and request withdrawal of the objection.

III. Rejection Under 35 U.S.C. § 112, second paragraph

Claims 11-13 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended. The Office Action states on page 4 that claim 11 is vague and indefinite for having a limitation of detecting both the level and the localization of KLF4, while the remaining limitations of the claim address the detected level and make no mention of the detected localization. As such, Applicants have amended claim 11 to recite that “decreases of nuclear localized KLF4 protein level indicate effective response of said individual to said treatment”. Thus, the claim as amended requires that the level of KLF4 having a specific localization is indicative of treatment response. Support for this amendment can be found in the detailed description at least in paragraphs 34, 35, 39, and 42-44. Accordingly, applicants believe the rejection is overcome by the claim amendments and request withdrawal of the rejection.

IV. Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-7, 11, 12, 32, and 33 are rejected as allegedly lacking sufficient enablement under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

A. Claims 1-7

The Office Action on page 6 states that claims 1-7 are rejected as allegedly lacking sufficient enablement under 35 U.S.C. § 112, first paragraph because “the specification, while being enabling for a method indicating a greater likelihood of survival, does not reasonably provide enablement for a method indicating a greater likelihood of response to a specific therapy.” The Applicants have amended claim 1 to remove the limitation that predominantly cytosolic staining indicates “a greater likelihood of response to a specific therapy”. Claim 1 is now drawn only to “indicating a greater likelihood of survival”. Support for this amendment can be found in the detailed description at least in paragraphs 34, 35, 42, and 134. Accordingly, applicants believe the rejection is overcome by the claim amendments and request withdrawal of the rejection.

B. Claims 11, 12, 32 and 33

The Office Action on page 7 states that claims 11, 12, 32 and 33 are rejected as allegedly lacking sufficient enablement under 35 U.S.C. § 112, first paragraph because:

the specification, while being enabling for methods for monitoring treatment thereby evaluating the effectiveness of treatment of an individual wherein decreases in the level of LKF4 is indicative of an effective response to treatment and wherein said individual suffers from breast carcinoma or oral squamous cell carcinoma, does not reasonably provide enablement for methods ... wherein said individual suffers from any other type of affliction.

The Applicants have amended claims 11 and 32 to incorporate the limitations of claim 34. Specifically, claims 11 and 32 now recite the limitation that the “individual suffers from breast carcinoma or oral squamous cell carcinoma.” Support for this amendment can be found in the detailed description at least in paragraphs 32, 51, and 52. Accordingly, applicants believe the rejection is overcome by the claim amendments and request withdrawal of the rejection.

V. Conclusion

In view of the above amendments and remarks, reconsideration and allowance of the pending claims is believed to be warranted, and such action is respectfully requested. The Examiner is encouraged to directly contact the undersigned if this might facilitate the prosecution of this application to issuance.

Enclosed is a Request for Extension of Time (Three Months). A fee of **\$510.00** for a three-month extension of time filing fee is due. The Commissioner is hereby authorized to apply this fee and any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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